DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

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WARNING LETTER
NWE-10-03W

February 3, 2003

VIA FEDERAL EXPRESS

Wayne Korteweg
President
Ultracell Medical Technologies
183 Providence New London Turnpike
North Stonington, CT 06359

Dear Mr. Korteweg:

During inspections of your establishment located at 183 Providence New London Turnpike, North Stonington, CT and 178 Colonel Ledyard Highway, Mystic, CT on December 17, 18, 23, and 31, 2002, our investigators determined that your establishment manufactures ophthalmic surgical sponges. These products are medical devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspections revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Quality System/Good Manufacturing Practice (QS/GMP) regulation for medical devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

- Failure to establish and maintain procedures for monitoring and control of process parameters to ensure that specified requirements continue to be met. [21 CFR 820.75(b)] For example, on a number of occasions during the past 2 years, your testing of in-process water used during the manufacture of your devices, revealed microbial results well above your established action levels.

- Failure to review and evaluate your process or perform revalidation when changes or process deviations occur. [21 CFR 820.75(c)] For example, your firm switched sources of in-process water, [redacted] in October 2000. Revalidation was not performed to determine the effect this change had on the products bioburden prior to

sterilization. We note that your sterilization process for all products is based on the original bioburden of the device. This type of dosimetric release is based on the theory that all processing parameters are known and within specification. If any processing parameter is out of specification, the system needs to be reevaluated.

- Failure to document corrective and preventive actions, including investigations of causes of nonconformances, the actions needed to correct or prevent recurrence of nonconforming product and other quality problems, and the verifications or validation of corrective actions. [21 CFR 820.100(b)] For example, on a number of occasions during the past 2 years, your testing of in process water used during the manufacture of your devices, revealed microbial results well above your established action levels. There were no documented corrective or preventive actions to demonstrate this was handled properly.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA Form 483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment's quality systems. You are responsible for investigating and determining the causes of the violations identified by the Food and Drug Administration (FDA). You also must promptly initiate permanent corrective and preventative action on your Quality System.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Also, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

We acknowledge receipt of your January 7, 2003 response to the FDA Form 483. We also acknowledge your firm's recall of all medical devices produced between May 7, 2002 – December 17, 2002. A review of your response reveals that it fails to fully address the violations listed above in sufficient detail to evaluate its adequacy. Therefore, in your response to this letter, you will need to describe in detail, how your firm will handle any process deviations or changes in the future.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the above noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15

working days, state the reason for the delay and the time within which the corrections will be completed.

You may direct your reply to Karen N. Archdeacon, Compliance Officer, at the address noted above. If you have any questions concerning this matter, please contact Ms. Archdeacon at (781) 596-7707.

Sincerely,

Gail T. Costello
District Director
New England District Office